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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Mats Jarekrans

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05/20/2002

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EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



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This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-21 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-21 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

2 ATTACHMENT

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1644

The preliminary amendment of 11/17/00 has been entered.

Claims 1-21 are pending and under examination.

The disclosure is objected to because of the following informalities: at page 12, lines 3-4, there is a sentence starting without capitalization and without a subject.

Appropriate correction is required.

At numerous points in the specification. The term "lysation" is nonidiomatic. The term-- lysis would be proper.

At page 5, line 31, the upper end of the range lacks any value.

No new matter may be added in any corrections.

Claims 1-3, 10 and 12-14 are objected to because of the following informalities: In claims 1 and 12 "lysation" is improper and may be replaced by --lysis--. In claims 2 and 13 "in stead" should appear as --instead--. In claims 3 and 14 "is ammonium chlorine" should be recited as -- contains ammonium chloride--. In claims 10 "(SIP)" should appear after, not before, the phrase that defines it. Appropriate correction is required.

Claims 2, 13-14, 18 and 20-21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2 and 13 fail to further limit base claims 1 and 12 because they substitute the use of a buffy coat fraction in lieu of blood

Art Unit: 1644

in step (a). Also these claims are inconsistent with the recitation of "blood" in the preamble of each of claims 1 and 12.

It is suggested that the preamble and step (a) of claims 1 and 12 be recited such that the claimed process separates plasma from blood or from a buffy coat fraction.

Claim 18 fails to further limit base claim 12 because claim 18 recites "semi-continuous" while base claim 12 require an apparatus for "continuous" purification.

Claims 13 and 14 fail to limit base claim 12 because they state what is put into the apparatus (buffy coat and ammonium chloride, respectively), rather than defining any structural limitations upon the apparatus.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 are confusing in step (a)/ element (ii) because it is not clear how one can "separate plasma from the blood by filtration in order to achieve a buffy coat fraction." From applicant's description at page 2, it appears that there would need to be an unrecited settling step (page 2, line 20), prior to the filtration step of separating the plasma from the buffy coat. The claims are thus rejected for failure to recite a critical disclosed step. See MPEP 2172.01 regarding missing steps.

Art Unit: 1644

Claims 2 and 13 are confusing in relation to base claims 1 and 12 because they are inconsistent with their base claims. See further discussion supra in the objection under 37 CFR 1.75 (C).

*def 8/21/03*  
Claims 1 and 12 and 18 are confusing as to what renders the purification "continuous" or "semicontinuous". As noted supra, regarding 37 CFR 1.75 (C), claim ~~18~~<sup>12</sup> recites "continuous purification" in the preamble, while dependent claim 18 recites "continuous or semicontinuous". If "continuous" in the base claim encompasses both "continuous" and "semicontinuous" in the dependent claim, it is then not clear how continuous a "continuous" process is or whether there is any distinction between a "continuous" and a "semicontinuous" purification/separation.

It is further noted that nothing in the body of claim 1, only the preamble, requires that the steps be continuous.

Claim 10 is confusing by reciting "adapted for clear in place (CIP) cleaning and (SIP) sanitation in place". There are no positively recited cleaning or sanitizing steps recited, and thus this aspect of the claim fails to describe anything the process of claim 1 --e.g. when any cleaning or sanitizing steps would be conducted in the sequence of steps recited in claim 1. It is further not clear what would be cleaned or sanitized.

Claim 12 is confusing in part (ii) and is non-idiomatic. At line 2 thereof, does applicant intend --for-- in lieu of "and" and the insertion of --and-- after "fraction"?

Art Unit: 1644

Claim 12, part (ii) is confusing because it states that the "lysatation" occurs in the mixer, while the specification has taught that the "lysatation" is achieved in the retention vessel of part (iii).

Claims 1, 3-12 and 14-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has disclosed no process or apparatus that enables "separating plasma from blood by filtration in order to achieve a filtered buffy coat fraction", as recited in step (a) of claims 1 and 12.

Applicant's disclosure, to the contrary, has disclosed that a settling step (page 2) is necessary in order to provide a buffy coat fraction from the blood. Applicant has disclosed no membrane that is capable of providing a filtered buffy coat fraction from whole blood. Since it is not conventional for a single filtration process to achieve the separations that would be achieved by (I) first settling to produce a buffy coat fraction from whole blood and by (ii) secondly filtering the plasma from the produced buffy coat of step (I), one would be required to conduct undue experimentation in order to find a filter capable of achieving what is recited in step (a) of claims 1 and 12.

Claims 12-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

Art Unit: 1644

invention. Applicant has not disclosed a static mixer (claim 12, part (ii)) that achieves "lysatation" as recited.

To the contrary applicant has disclosed (page 8, lines 15-17) that "lysatation" is achieved in the retention vessel of claim 12, part (iii), rather than in the static mixer. Applicant has thus not disclosed a static mixer that enables "lysatation" in a continuous process. Without the retention vessel, which provides for an adequate time for lysis, after the mixing step, one would expect there would be an undue amount of unlysed red blood cells carried over into the centrifuge.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al. (4,294,824).

As noted by the IPEA Jones et al. teach the process of claims 1-11, except for the fact that Jones et al. carry out the recited steps in a different order. In U.S. practice the claim is read as encompassing the conducting of the recited steps in an order not necessarily the same as that recited. Therefore the process claims are anticipated.

Apparatus claims <sup>12</sup>~~13~~-19 are free of the prior art of record.

Martinson et al. (5,785,869) are cited as of interest for teaching preparation of a leukocyte sample via centrifugation.

see  
8/21/07

Art Unit: 1644

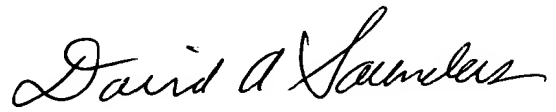
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

April 30, 2002

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182/1644